SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

October 7, 2015

The Honorable Mike Callton
House Health Policy Committee Chairman
Anderson House Office Building, P.O. Box 30014
Lansing, MI 48909-7514

Dear Chairman Callton,

As the chairman and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are writing to request that you **support House Bill 4812 (HB 4812)** regarding the pharmacy substitution of biosimilar medical products. ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovative and biosimilar medicines, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

As a practicing pediatric rheumatologist and a former president of the American Society of Health-System Pharmacists, we are keenly aware of the benefits of biologics in treating serious conditions like cancer, rheumatoid arthritis, diabetes, and MS. "Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at reduced cost. Yet unlike generic versions of chemical drugs biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. And even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient. Therefore, the issue of interchangeability has been a new challenge for policymakers.

We believe that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support HB 4812 and are concerned that patient safety will be compromised if this legislation is not enacted.

Since 2012, ASBM has conducted surveys of physicians in eleven countries, to gather their perspectives on biosimilars. The results of these surveys have since been shared with policymakers in the U.S., Canada, Europe, and the World Health Organization in Geneva, Switzerland.

- **Our survey of 376 U.S. physicians found that 80% of those surveyed called notification in the event of a biosimilar substitution "very important" or "critical".**

- **Further, 82% of U.S. physicians called the authority to block a substitution by indicating "do not substitute" or "dispense as written" on a prescription "very important" or "critical".**

These results are consistent with those of physicians around the world, including those surveyed in Canada and Europe, where biosimilars are currently in clinical use. All ASBM surveys are available on our website at www.safebiologics.org.

It is our view that HB 4812 appropriately reflects the importance of pharmacist-physician communication and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist:

- It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) or which are "therapeutically equivalent" to their reference products may ever be substituted.

- It allows a physician to prevent a substitution they consider inappropriate for their patient by writing "dispense as written" on the prescription.

- It ensures patients will be notified in the event a biosimilar is substituted for the prescribed biologic, and that any savings will be passed on to them.

- Finally HB 4812 requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which biologic the patient actually received – whether that prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

It is our understanding that a competing bill, HB 4437, has been introduced that shares some, but not all of these elements. It is our position that HB 4437, while well intentioned, does not adequately address these concerns.

By contrast, HB 4812 will extend valuable protections to Michigan's patients while increasing access to biologic therapies and saving taxpayers money. For these reasons, HB 4812 has gained bipartisan support from more than 20 cosponsors, including several Members who are physicians.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Michigan by supporting House Bill 4812.

Sincerely,

Harry Gewanter, MD
Chairman, The Alliance for Safe Biologic Medicines

Philip J. Schneider, MS, FASHP
Advisory Board Chair, Alliance for Safe Biologic Medicines
Professor, University of Arizona College of Pharmacy

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